DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 2006

Mpathy Medical Devices Ltd.
c/o Mr. Louis J. Mazzarese
Designated U.S. Agent
150 Aran Hill Road
Fairfield, Connecticut 06824-1712

Re: K053361
Trade/Device Name: Minimesh® polypropylene mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: January 5, 2006
Received: January 10, 2006

Dear Mr. Mazzarese:

This letter corrects our substantially equivalent letter of February 6, 2006.
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

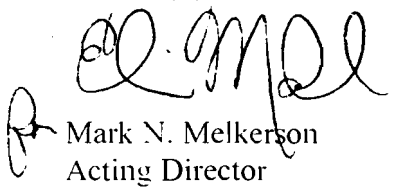
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number k053361

K053361
Page 1 of 2

FEB 6 2006

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

SUBMITTER	Mpathy Medical Devices, Ltd. 6.05 Kelvin Campus West of Scotland Science Park Glasgow G20 0SP U.K.
CONTACT PERSON	Louis J. Mazzarese (U.S. Agent for Mpathy Medical Devices Ltd.)
DATE PREPARED	January 30, 2006
CLASSIFICATION	Polymeric Surgical Mesh (Product Code FTL) is a Class II device per 21 CFR 878.3300
COMMON NAME	Polymeric Surgical Mesh
PROPRIETARY NAME	Minimesh® polypropylene mesh
PREDICATE DEVICES	K041632 Minimesh® polypropylene mesh
DEVICE DESCRIPTION	Minimesh® is a non-absorbable polypropylene mesh constructed from knitted monofilaments of extruded polypropylene. Minimesh® polypropylene mesh is constructed using a warp-knit process to a unique design that permits the mesh to be cut into any desired shape or size without unraveling. Minimesh® polypropylene mesh has the necessary strength, flexibility, durability and surgical adaptability. These properties permit the correct adaptation to the various stresses encountered in the body. The device is supplied sterile.
INDICATIONS FOR USE	Minimesh® polypropylene mesh may be used for the repair of abdominal wall hernia, including inguinal, femoral, and incisional, uterological prolapse and other fascial deficiencies that require support material. It may be used in open or laparoscopic abdominal procedures or for repair by the vaginal route.

K053361
Page 2 of 2

510(k) SUMMARY OF SAFETY & EFFECTIVENESS (Cont'd.)

TESTING

Accelerated and real time stability studies have been conducted and support use of a three year expiration date for the product. The results of these studies demonstrate that Minimesh® polypropylene mesh, when stored under the conditions specified in the product labeling, can be used safely and effectively throughout this dating period (see Addendum A).